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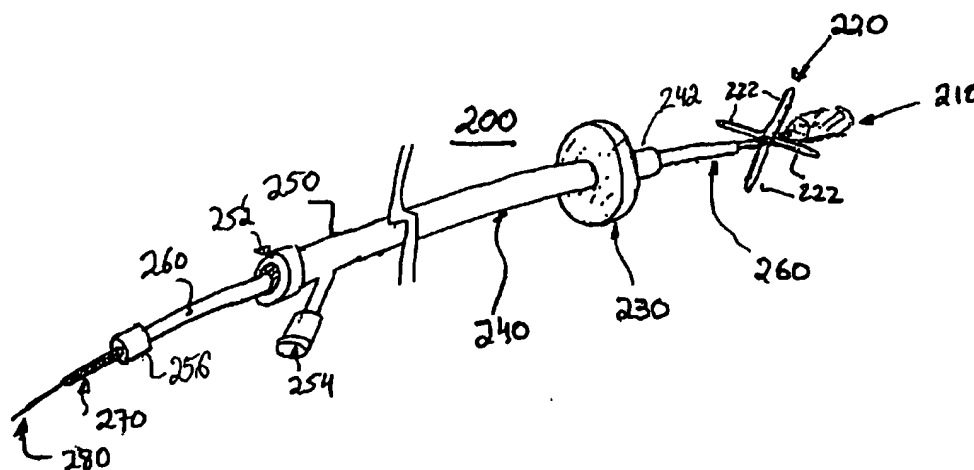
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(54) Title: APPARATUS FOR IMPLANTING DEVICES IN ATRIAL APPENDAGES



(57) Abstract: The invention provides a delivery system for placing devices in atrial appendages. The system includes a catheterization apparatus having a tubular structure with one or more nested tubes, wires, and shafts. The tubes establish a passageway for moving a device through a body's vasculature and heart into an atrial appendage. An expandable positioning guide is disposed on the distal end of a tube passing through the apparatus. The positioning guide is expanded in situ to engage atrial wall surfaces proximate to the atrial appendage for mechanical stabilization of the device delivery passageway. A shaft passing through the tubes transports the device through the passageway to the atrial appendage. The system includes catheterization apparatus for transseptal delivery of the devices. An outer tube or sheath in the apparatus is used to penetrate and traverse the septum. An expandable securement device is disposed toward an end of the sheath. The securement device is expanded in situ to engage surface portions of the traversed septum to restrain further inadvertent movement of the septum-traversing sheath.

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APPARATUS FOR IMPLANTING DEVICES
IN ATRIAL APPENDAGES

This application claims the benefit of U.S.
5 provisional application No. 60/234,111, filed September
21, 2000, which is hereby incorporated by reference in
its entirety herein.

Background of the Invention

Field of the Invention

10 The invention relates to apparatus for
implanting devices in atrial appendages. The devices
may be used to filter or otherwise modify blood flow
between the atrial appendage and an associated atrium
of the heart to prevent thrombi from escaping from the
15 atrial appendage into the body's blood circulation
system. In particular the invention relates to
apparatus for percutaneous delivery and implantation of
such devices.

Description of the Related Art

20 There are a number of heart diseases (e.g.
coronary artery disease, mitral valve disease) that
have various adverse effects on a patient's heart. An
adverse effect of certain cardiac diseases, such as
mitral valve disease, is atrial (or auricular)

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fibrillation. Atrial fibrillation leads to depressed cardiac output. A high incidence of thromboembolic (i.e., blood clot particulate) phenomena is associated with atrial fibrillation, and the left atrial appendage
5 (LAA) is frequently the source of the emboli (particulates).

Thrombi (i.e., blood clots) formation in the LAA may be due to stasis within the fibrillating and inadequately emptying LAA. Blood pooling in the atrial
10 appendage is conducive to the formation of blood clots. Blood clots may accumulate and build upon themselves. Small or large fragments of the blood clots may break off and propagate out from the atrial appendage into the atrium. The blood clot fragments can then enter
15 the body's blood circulation and embolize distally into the blood stream.

Serious medical problems result from the migration of blood clot fragments from the atrial appendage into the body's blood stream. Blood from the
20 left atrium and ventricle circulates to the heart muscle, the brain, and other body organs, supplying them with necessary oxygen and other nutrients. Emboli generated by blood clots formed in the left atrial appendage may block the arteries through which blood
25 flows to a body organ. The blockage deprives the organ tissues of their normal blood flow and oxygen supply (ischemia), and depending on the body organ involved leads to ischemic events such as heart attacks (heart muscle ischemia) and strokes (brain tissue ischemia).

30 It is therefore important to treat cardiac conditions to prevent fragments or emboli generated by any blood clots that may have formed in the atrial appendages, from propagating through the blood stream to the heart muscle, brain or other body organs.

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Some recently proposed methods of treatment are directed toward implanting a plug-type device in an atrial appendage to occlude the flow of blood therefrom.

5 A preventive treatment method for avoiding thromboembolic events (e.g., heart attacks, strokes, and other ischemic events) involves filtering out harmful emboli from the blood flowing out of atrial appendages. Co-pending and co-owned U.S.
10 patent application No. 09/428,008, U.S.
patent application No. 09/614,091, U.S.
patent application No. 09/642,291, U.S.
patent application No. 09/697,628, and U.S.
patent application No. 09/932,512, all of which are
15 hereby incorporated by reference in their entireties herein, describe expandable filtering devices which may be implanted in an atrial appendage to filter the blood flow therefrom.

The implant devices in a compact state may be
20 delivered to their atrial appendage situs percutaneously through femoral or jugular blood vessels using conventional catheterization apparatus. The position of an implanted device may be observed using common imaging techniques, for example, radiography or
25 echocardiography. The implant devices are deployed by expanding them in situ. The devices are retained in position by expandable structures which engage surrounding atrial appendage tissue. The expandable structures may include tissue piercing anchors.

30 To function effectively the devices must be deployed from suitable positions within or about the atrial appendages. For example, the filter elements of a device must be correctly centered or positioned across an atrial appendage ostium for the device to

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properly intercept and filter blood flowing out of the atrial appendage. Placing a device in a suitable deployment position may require position probing or adjustment from an initial as-delivered position.

5 It would therefore be desirable to provide catheterization apparatus having positioning guides, which enable controlled position probing and readjustment of the initial as-delivered implant device position to place the device in a suitable deployment
10 position in the atrial appendage.

 Further, the implant procedures may include transseptal catheterization which involves puncturing an atrial septum and advancing an access sheath through the septum. The access sheath provides a conduit
15 through which an implant device may be delivered across the septum into the adjoining atrium. Inadvertent movement of the sheath during the catheterization procedure may lead to undesirable medical complications. For example, retrograde slippage may
20 cause the sheath to disengage from the septum, which in turn may necessitate repeated puncturing or crossing of the septum to regain access to the adjoining atrium. Further, instability in the position or orientation of the access sheath may make the delivery of a device for
25 placement in an appendage geometrically difficult.

 It would therefore also be desirable to provide transseptal catheterization apparatuses which include securement devices for restraining the movement of and securing the position of the access sheath
30 traversing the septum.

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Summary of the Invention

The invention provides a catheterization apparatus having a positioning device or guide, which enables controlled position probing and readjustment of the initial as-delivered implant device position. The catheterization apparatus may include one or more nested tubes, wires or shafts. The positioning guide may be attached to a positioning tube passing through the catheter apparatus. Using the positioning guide, the implant device position in the atrial appendage may be readjusted from the as-delivered position to a desired deployment position.

The positioning guide may have an expandable structure. The structure may be expandable from a compact state to an expanded state. The positioning guide is delivered in its compact state to a location adjoining the ostium of an atrial appendage. The apparatus may include size-adjusting mechanisms for expanding the positioning guide in situ. The positioning guide may be deployed by expanding it to engage or contact portions of the atrial wall proximate to the ostium for mechanical support. The deployed guide thereby holds and stabilizes outer portions of the catheter apparatus in a fixed position. An implant device attached to a shaft passing through the catheterization apparatus may then be reversibly positioned within the atrial appendage. The implant device position may be monitored, for example, by echocardiography, radiography or fluoroscopy. After the implant device is suitably positioned and deployed, the positioning guide may be contracted to its compact non-expanded state and retracted.

In an embodiment of the catheterization apparatus which may be useful for transseptal

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catheterization, a securement means is attached to an access sheath in the catheterization apparatus. The access sheath is used to puncture an atrial septum and then advanced through the puncture to provide a passage way through which an implant device may be delivered to an adjoining atrium. The securing means may, for example, include an inflatable disk having an inflated diameter that is larger than the size of the septal puncture. The inflatable disk may be deployed to engage distal surfaces of the punctured septum to secure the position of the access sheath relative to the septum.

Other embodiments of the positioning guides (and securement means) may have other kinds of inflatable or expandable structures which allow the positioning devices (and securement means) to have compact sizes for delivery and which can later be enlarged in situ.

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawing and the following detailed description.

Brief Description of the Drawings

FIG. 1 is a partial cross sectional view of a heart illustrating a conventional catheter entering a left atrial appendage using a transseptal procedure.

FIGS. 2a and 2b illustrate examples of wire patterns or configurations of expanded positioning guides in accordance with the principles of the invention

FIG. 2c schematically illustrates an inflatable balloon-type positioning guide in accordance with the principles of the invention.

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FIG. 3 is a schematic view of a portion of a transseptal catheterization apparatus having a positioning guide for reversible or adjustable placement of an implant device in an atrial appendage, and a securement means for restraining movement of a septum-traversing access sheath in accordance with the principles of the invention.

FIG. 4 is a schematic view of a portion of the transseptal catheterization apparatus of FIG. 3 illustrating the deployment of the securement means to restrain movement of a septum-traversing sheath in accordance with the principles of the invention.

FIG. 5 is a schematic view of a portion of the transseptal catheterization apparatus of FIG. 3 illustrating figuratively the deployment of the positioning guide to engage atrial wall surfaces proximate to the ostium of an atrial appendage in accordance with the principles of the invention.

Description of the Preferred Embodiments

Implant devices for filtering or otherwise modifying blood flow between an atrial appendage and its atrium may be attached to a catheter shaft and then be percutaneously delivered to the appendage through a blood vessel leading to the heart.

FIG. 1 illustrates, for example, catheter 21 inserted through a femoral vein (not shown) entering the right atrium of the heart through the inferior vena cava 18, and then passing into left atrium 11 through the fossa ovalis 19 or through the septum 29 before entering the left atrial appendage 13. Alternatively (not shown in FIG. 1), catheter 21 may enter the left ventricle 16 of the heart through the aorta 12, and then pass through mitral valve 17 to reach left atrial

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appendage 13. An implant device (not shown) attached to catheter 21 may be used to prevent thrombus 30 or emboli generated therefrom from migrating into atrium 11. The device may include materials having
5 suitable properties (e.g., radio-opacity) that make it possible to monitor the in-vivo device position during and after the catheterization position using external imaging techniques such as radiography or fluoroscopy, echocardiography, and ultrasound.

10 The present invention provides a catheterization apparatus having a positioning device or guide, which enables controlled position probing and readjustment of an initial as-delivered implant device position. The implant device position in the atrial
15 appendage may be readjusted from the as-delivered position to a desired deployment position. The catheterization apparatus may include one or more nested tubes, wires or shafts. The positioning guide may be attached to a positioning tube passing through
20 the catheter apparatus.

 The positioning guide may have an expandable or inflatable structure designed to engage (contact) atrial wall portions surrounding the ostium. The structure may be designed to be reversibly expandable
25 from a compact state suitable for percutaneous delivery and withdrawal. Further, the positioning guide may be designed to engage surrounding atrial wall portions to provide a stable and reproducible pathway for movement of a device-carrying shaft in and out of the atrial
30 appendage.

 The positioning guide may be made of suitable biocompatible materials including metals and polymeric materials such as ePTFE (e.g., Gortex®), polyester (e.g., Dacron®), PTFE (e.g., Teflon®), stainless steel

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and shape-memory alloys (e.g., nitinol) fibers or wires.

Positioning guides according to one embodiment may be formed from lengths of wires. The
5 wires may be made of suitable elastic materials including shape memory alloy materials such as nitinol. There may be one or more wires or wire configurations which make up the positioning guide. In the compact state of the positioning guide that is suitable for
10 percutaneous delivery, the wires may lie substantially along the positioning tube. The wires or wire configurations made, for example, from shape-memory alloy materials, may have preformed shapes. In the expanded state of the positioning guides, these wires
15 may revert to their preformed shapes in which they may extend away from the positioning tube. The extended wires may have any suitable configuration for engaging the atrial wall portions. For example, the extended wires may have a straight spoke-like pattern or have
20 more complex patterns such as overlapping arcuate patterns. FIG. 2a illustrates, for example, a spoke-like configuration of wires 510 in the expanded or deployed state of a positioning guide 500. Wires 510 extend radially outward away from positioning tube
25 520 on which guide 500 is disposed. Further, for example, FIG. 2b illustrates an overlapping arcuate pattern of wires 510 in the expanded or deployed state of positioning guide 550.

The catheterization apparatus may include
30 suitable size-adjusting mechanisms that allow the positioning guide to be reversibly expanded in situ. For example, the apparatus may include a retractable sleeve which covers and holds the elastic or shape-memory alloy wires forming a positioning guide in

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a compact configuration along or in close proximity to the positioning tube. The positioning guide may be deployed by retracting the sleeve to allow the wires to expand or unfurl radially outward. The sleeve may be
5 moved forward to reverse the expansion as needed to return the positioning guide to its compact state. Alternatively, the wires may be contained within the delivery tube, and attached, for example, to a sliding push rod that enables the wires to be retractably
10 extended through small diameter openings or holes in the delivery tube walls.

The positioning guide in its non-expanded compact state is delivered to a location adjoining the ostium of an atrial appendage. The positioning guide
15 is deployed by expanding it to engage or contact portions of the atrial wall proximate to the ostium for mechanical support. The outermost engagement points may be separated by distances that are larger than the positioning tube diameter. Preferably, the separation
20 distances are several times larger than the positioning tube diameter to obtain a support configuration having a wide geometry that favors mechanical stability. Additionally, the position guide may be suitably advanced forward to bear upon the atrial wall portions
25 with a contact pressure adequate to generate frictional resistance to its lateral movement. Thus, the deployed positioning guide may mechanically hold and stabilize the positioning tube in a fixed position relative to the ostium. An implant device attached to a shaft
30 passing through the positioning tube may then be reversibly placed at a location within the atrial appendage. The implant device position may be monitored, for example, by electrocardiographic, radiographic, or fluoroscopic imaging. After the

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implant device is suitably positioned or deployed, the positioning guide may be contracted and retracted.

Other embodiments of the positioning guides may have other kinds of inflatable or expandable
5 structures which allow the positioning guides to have compact sizes for delivery and which can later be enlarged in situ. For example, positioning guides according to one of these other embodiments may have inflatable balloon-type structures. The balloons may
10 be made of suitable elastic membranes, for example, made of urethane or silicone material. FIG. 2c schematically illustrates, for example, a balloon-type structure 560 of a positioning guide 570.

An embodiment of a catheterization apparatus
15 may be useful for transseptal catheterization. The apparatus of this embodiment has an access sheath which is used to provide a conduit or pathway for device delivery across a septum between adjoining atriums. The apparatus includes a securement means which may be
20 used to restrain movement of the septum-traversing access sheath. The securement means is disposed on or about the distal end of the access sheath.

The access sheath may be an outermost tube of the catheterization apparatus. Known catheterization
25 techniques may be used to have the access sheath penetrate and traverse a septum. A known technique, for example, uses a conventional dilator (obturator) device having a covered needle in its tip. The dilator is preloaded in the access sheath such that the dilator
30 tip extends out of the distal end of the access sheath. The preloaded access sheath is advanced into an atrium through the body's vasculature. Next, the dilator needle is advanced through the dilator tip to puncture the atrial septum, following which the dilator itself

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is advanced to dilate the puncture opening. The access sheath is then advanced through the dilated puncture opening across the septum into the adjoining atrium. Finally, the dilator device is then withdrawn from the
5 access sheath.

The securement means in the catheterization apparatus of the present invention may be deployed to restrain further movement of the septum-traversing access sheath. The securing means may, for example,
10 include an inflatable disk having an inflated diameter that is larger than that size of the septal puncture or the diameter of the access tube. Preferably, the inflated diameter is several times larger than the diameter of the access tube. In catheterization
15 apparatus useful for procedures on adult hearts, the inflated diameter may, for example, be in the range of about 5 to 10 mm. The inflatable disk may be fabricated from membranes made of biocompatible materials such as silicone, urethane, or other
20 biocompatible polymers.

The catheterization apparatus may include suitable means for reversibly inflating the securement means. For example, the access sheath may include a tube connected to the inflatable disk structure through
25 which pressurizing fluids may be supplied to inflate the disk. The inflatable disk may be deployed to engage the distal surfaces of the punctured septum to secure the position of the access sheath relative to the septum and to restrain inadvertent movement of the
30 access sheath.

Other embodiments of the securement means may have other kinds of inflatable or expandable structures which allow the securement means to have compact sizes for delivery and which can later be enlarged in situ.

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FIG. 2 illustrates, for example, transseptal catheterization apparatus 200 having a positioning guide 220 for reversible placement of an implant device 210 in an atrial appendage, and a securement means 230 for restraining inadvertent or uncontrolled movement of a septum-traversing access sheath 240.

Apparatus 200 includes coaxially nested access sheath 240, delivery tube 260, positioning tube 270, and device shaft 280, all of which are connected to or pass through handle manifold 250.

Access sheath 240 may form an outer tubular structure of catheterization apparatus 200. Rigid biocompatible tube materials such as metals and plastics may be used to fabricate access sheath 240. However, access sheath 240 may be sufficiently flexible for it to course through blood vessels leading to the heart. Access sheath 240 may have an outer diameter suitable for percutaneous passage to the heart through readily accessible blood vessels, for example, the femoral veins.

One end (proximal end) of access sheath 240 is attached to handle manifold 250. Inflatable securement means 230 is disposed on or built into access sheath 200 toward its distal end. Securement means 230 may be reversibly inflated, for example, by pressurizing fluids injected through inflation port 254 disposed on manifold 250.

Handle manifold 250 includes fluid seal structure 252 through which a delivery tube 260 passes through and retractably extends into access sheath 240. Fluid seal 252 may be any conventional seal designed to prevent leakage of fluids while delivery tube 260 is retracted or extended into access sheath 240. Fluid seal 252 may, for example, be a

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conventional hemostatic seal. Rigid biocompatible tube materials such as metals and plastics similar to those used to fabricate access sheath 240 also may be used to fabricate delivery tube 260. Delivery tube 260 may
5 have sufficient flexibility for it to course through access sheath 240 in the latter's deployed position through blood vessels leading to the heart. Delivery tube 260 may have an outer diameter sized to allow its smooth movement within access sheath 240. The outer
10 diameter of delivery tube 260 also may be sufficiently smaller than the inner diameter of access sheath 240 to allow pressurizing fluids to flow between securement means 230 and inflation port 254. Alternatively or additionally, the outer surface of delivery tube 260
15 may be grooved to provide flow channels for pressurizing fluids to flow between securement means 230 and inflation port 254.

The inner diameter of delivery tube 260 is sized to be sufficiently large to accept and allow
20 passage of positioning guide 220 disposed on the distal end of a positioning tube 270. Rigid biocompatible tube materials such as metals and plastics similar to those used to fabricate access sheath 240 and delivery tube 260 also may be used to fabricate positioning tube
25 270. Positioning tube 270 may be sufficiently flexible for it to course through delivery tube 260 in the latter's deployed position through access sheath 240. Positioning tube 270 retractably extends into delivery tube 260 through seal 256 disposed on the proximal end
30 of delivery tube 260. Seal 256 is designed to prevent fluid leakage, and may, for example, be of a type similar to fluid seal 252.

Positioning guide 220 disposed on the distal end of positioning tube 270 may have a compact state

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from which it may be reversibly expanded to an expanded state. FIG. 2 shows for purposes of illustration an exemplary positioning guide 220 in its expanded state. Expanded positioning guide 220 has a structural
5 configuration with four extended fingers 222 suitable for engaging or contacting atrial walls for mechanical support to stabilize the position of positioning tube 270. The four extended fingers shown in FIG. 3 have a size which substantially larger than the diameter of
10 delivery tube 260. However, it will be understood that positioning guide 220 is passable through delivery tube 260 only when the former is in its compact retracted state. Positioning tube 270 may include means such as a trip wire, a push rod, a retractable sleeve, or other
15 suitable means to reversibly deploy positioning guide 220. Positioning tube 270 itself may, for example, serve as a push rod, in which case positioning guide 220 may be expanded or contracted by respectively advancing or retracting positioning tube 270 through
20 delivery tube 260.

The inner diameter of positioning tube 270 is sized to be sufficiently large to accept and allow passage of compacted implant device 210 attached to one end of a device shaft 280. Implant device 210 may, for
25 example, be any one of the self-expanding or inflatable filtering devices disclosed U.S. patent application No. 09/428,008, U.S. patent application No. 09/614,091, U.S. patent application No. 09/642,291, U.S. patent application No. 09/697,628, and U.S.
30 patent application No. 09/932,512, incorporated by reference herein. Device shaft 280 may be a conventional catheter shaft having conventional fixtures for device attachment. Device shaft 280 may, for example, have a solid or tubular structure made of

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solid metals, metal braids, solid polymers, polymer braids, or any suitable combination thereof. Shaft 280 may enclose other tubes or structures that may be required for device deployment. For example, device
5 shaft 280 may include some lumen for supplying fluids for inflation of an expandable balloon in a balloon-inflatable type of device 210.

Catheterization apparatus 200 (or other embodiments thereof) may be used to controllably and
10 adjustably place an implant device at a suitable deployment location within an atrial appendage. Position guide 220 and/or securement means 230 may be used to provide a mechanically stable pathway for delivery of the device, and for adjusting the device
15 location within the atrial appendage before device deployment.

With reference to FIG. 4, in a transseptal catheterization procedure, access sheath 240 with securement means 230 in its compact state is introduced
20 into a right atrium 330 through the body's vasculature. The progress of access sheath 240 through the body may be monitored, for example, by echocardiography, radiographic or fluoroscopic imaging. A conventional needle and dilator assembly (not shown) reversibly
25 sliding through access sheath 240 may be used to puncture and dilate septum 310. Access sheath 240 is advanced forward through the dilated puncture opening in septum 310. A distal length 241 of access sheath 240 is advanced across septum 310 into left atrium 320.
30 After securement means 230 disposed on the distal end of access sheath 240 advances across septum 310, forward advancing motion of access sheath 240 may be halted. Securement means 230 may then be deployed, for example, by injecting pressurizing fluid through

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inflation port 254. With securement means 230 inflated movement of access sheath 240 is restrained by engagement of means 230 with distal wall surfaces of septum 310. This engagement may prevent retrograde
5 movement or slippage of access sheath 300 that may occur inadvertently, or for example, in mechanical reaction to the action of advancing other strictures such as a tight fitting delivery tube 260 through access sheath 230. FIG. 4 shows access sheath 240 with
10 length 241 jutting into left atrium 320 secured against septum 310 by inflated securement means 230, and providing a mechanically stable conduit for delivery tube 260 to access left atrium 320.

Implant device 210 and other catheter
15 structures including positioning guide 220 may be passed through delivery tube 260 into left atrium 320. FIG. 5 figuratively illustrates the deployment of the positioning guide 220 to engage atrial wall surfaces 430 proximate to the ostium 410 of a left
20 atrial appendage 420 for mechanical support.

After access sheath 240 is secured against septum 310 by inflated securement means 230, and delivery tube 260 is introduced into left atrium 320, positioning tube 270 with positioning guide 220 in its
25 compact state is advanced through delivery tube 260 into left atrium 320. Positioning tube 270 is advanced sufficiently into left atrium 320 so that positioning guide 220 butts up against or is very close ostium 410. Positioning guide 220 is then deployed so that it
30 engages surface portions of the atrial wall 430 surrounding ostium 410. In FIG. 5, directions A figuratively depict the motion of fingers 222 during the deployment of guide 220. During the deployment fingers 222 move from a contracted configuration

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alongside positioning tube 270 to an expanded configuration with fingers 222 spread radially outward. Fingers 222 in the expanded configuration engage atrial wall 430 for mechanical support. By engaging or
5 contacting atrial wall 430 positioning guide 220 mechanically stabilizes the position of tubes 260 and 270 relative to that of atrial appendage 420. Implant device 210 attached to shaft 280 may be delivered to a location within atrial appendage 420 simultaneously
10 with the delivery of positioning guide 220 to a location butting up against or is very close ostium. Alternatively, implant device 210 may be delivered after positioning guide 220 has been deployed to engage atrial walls 430 for mechanical support. The location
15 of device 210 may be adjusted by sliding shaft 280 through the stabilized pathway provided by positioning tube 270 held in relatively fixed position by deployed positioning guide 220.

It will be understood that the foregoing is
20 only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. It will be understood that terms like "distal" and "proximal", and other
25 directional or orientational terms are used herein only for convenience, and that no fixed or absolute orientations are intended by the use of these terms.

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What Is Claimed Is:

1. A catheterization apparatus for transseptal delivery of a device, comprising:
a sheath for traversing a septum and establishing a transseptal conduit for passage of said device across said septum;
securement means disposed on said sheath for restraining movement of said sheath relative to said traversed septum; and
a shaft for transporting said device through said sheath across said septum.
2. The apparatus of claim 1 wherein said sheath comprises a flexible tube.
3. The apparatus of claim 1 wherein said securement means comprises a reversibly expandable structure.
4. The apparatus of claim 3 wherein said reversibly expandable structure when expanded engages surface portions of said traversed septum.
5. The apparatus of claim 3 wherein said expandable structure comprises an inflatable structure.
6. The apparatus of claim 5 wherein said sheath further comprises lumen for supplying pressurizing fluids to inflate said inflatable structure.
7. The apparatus of claim 5 wherein said inflatable structure is made from an elastic membrane.

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8. The apparatus of claim 5 wherein said inflatable structure has an inflated diameter that is several times larger than the diameter of said sheath.

9. A method for establishing a transseptal conduit for device delivery during a catheterization procedure, comprising:

providing a catheterization apparatus comprising:

a sheath for traversing a septum wherein said sheath comprises lumen for movement of a device therethrough; and

securement means disposed on said sheath for restraining movement of said sheath relative to said traversed septum;

puncturing and dilating said septum;

advancing said sheath through said punctured septum to move said securement means across said septum; and

deploying said securement means to engage surface portions of said septum and thereby restrain further movement of said sheath.

10. The method of claim 9 wherein said providing a catheterization apparatus further comprises providing said sheath in the form of a flexible tube.

11. The method of claim 9 wherein said providing a catheterization apparatus further comprises providing said securement means having a reversibly expandable structure.

12. The method of claim 11 wherein said providing said securement means having a reversibly

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expandable structure further comprises providing a structure which when expanded engages surface portions of said traversed septum.

13. The method of claim 11 wherein said providing said securement means having a reversibly expandable structure further comprises providing an inflatable structure.

14. The method of claim 13 wherein providing said sheath further comprises providing a sheath having lumen for supplying pressurizing fluids to inflate said inflatable structure.

15. The method of claim 13 wherein providing said inflatable structure further comprises providing an inflatable structure made from an elastic membrane.

16. The method of claim 13 wherein providing said inflatable structure further comprises providing an inflatable structure having an inflated diameter that is several times larger than the diameter of said sheath.

17. A catheterization apparatus for implanting a device in an atrium's appendage, comprising:

a tube assembly for providing a passage way for movement of said device through the body's vasculature and said atrium to said appendage, said assembly comprising at least an outer tube;

a shaft for transporting said device through said assembly; and

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a positioning guide for engaging atrial wall portions for mechanical support of portions of said tube assembly within said atrium.

18. The apparatus of claim 17 wherein said positioning guide is disposed on a positioning tube that retractably extends through said outer tube.

19. The apparatus of claim 17 wherein said positioning guide comprises a reversibly expandable structure.

20. The apparatus of claim 19 wherein said reversibly expandable structure comprises at least a preformed wire configuration.

21. The apparatus of claim 19 wherein said reversibly expandable structure comprises an inflatable balloon.

22. The apparatus of claim 21 wherein said tube assembly further comprises lumen for supplying pressurizing fluids to inflate said inflatable structure.

23. The apparatus of claim 17 wherein said tube assembly further comprises a delivery tube for advancing said positioning guide through said tube assembly to a location proximate to said appendage, wherein said delivery tube retractably extends through said outer tube.

24. The apparatus of claim 23 wherein said tube assembly further comprises a positioning tube that

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retractably extends through said delivery tube wherein said positioning guide is disposed on an end of said positioning tube.

25. The apparatus of claim 17 further comprising a securement means disposed on an end of said outer tube wherein said securement means engages surface portions of a septum traversed by said outer tube to restrain further movement of said outer tube.

26. The apparatus of claim 25 wherein said securement means comprises a reversibly expendable structure.

27. The apparatus of claim 26 wherein said expandable structure is an inflatable structure made from an elastic membrane.

28. A method for implanting a device in an atrium's appendage, comprising
providing a catheterization apparatus
comprising:

a tube assembly for providing a passage way for movement of said device through the body's vasculature and through said atrium to said appendage, said assembly comprising at least an outer tube;

a shaft for transporting said device through said assembly; and

a positioning guide for engaging atrial wall portions for mechanical support of portions of said sheath assembly within said atrium;

percutaneously advancing said tube assembly through a blood vessel to establish a passageway to said atrium;

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introducing said positioning guide to a location about the ostium of said appendage;
deploying said positioning guide to engage atrial wall portions for mechanical support; and
using said shaft to transport said device through said passageway to a position within said appendage

29. The method of claim 28 wherein providing said catheterization apparatus further comprises providing a positioning guide that is disposed on a positioning tube that retractably extends through said outer tube.

30. The method of claim 28 wherein providing said positioning guide further comprises providing a positioning guide having a reversibly expandable structure.

31. The method of claim 30 wherein providing said reversibly expandable structure comprises providing at least a preformed wire configuration.

32. The method of claim 30 wherein providing said reversibly expandable structure comprises providing an inflatable balloon.

33. The method of claim 32 wherein providing said tube assembly further comprises providing lumen for supplying pressurizing fluids to inflate said inflatable balloon.

34. The method of claim 28 wherein providing said tube assembly further comprises providing a

- 25 -

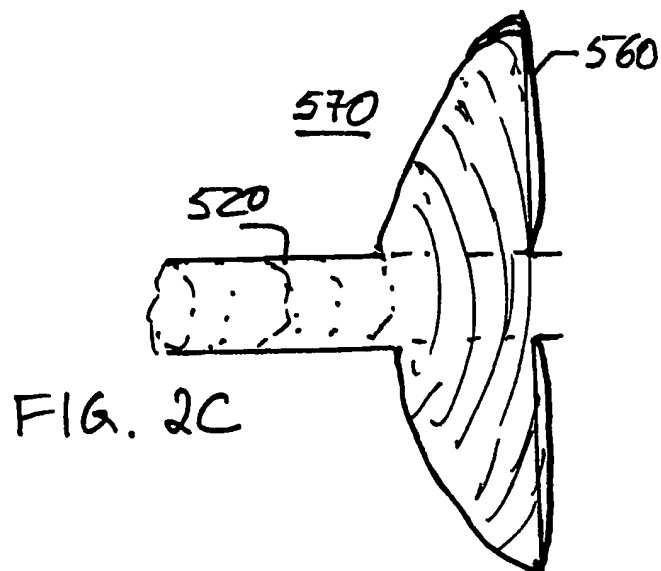
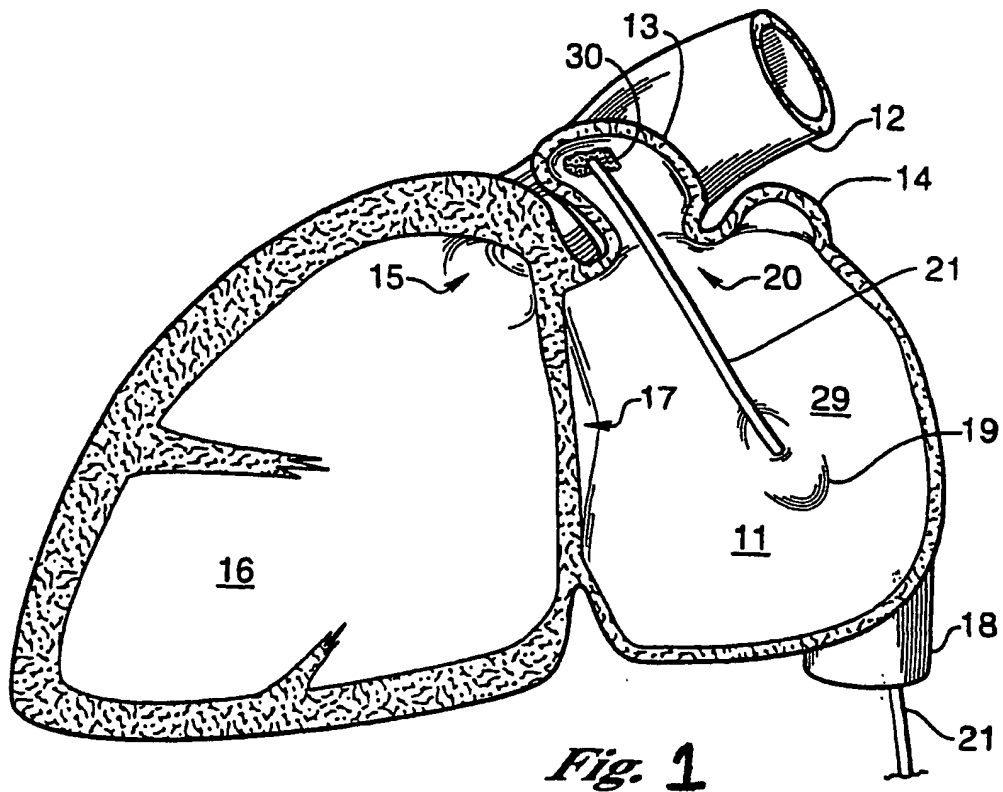
delivery tube for advancing said positioning guide through said tube assembly to a location proximate to said appendage, and wherein said delivery tube retractably extends through said outer tube.

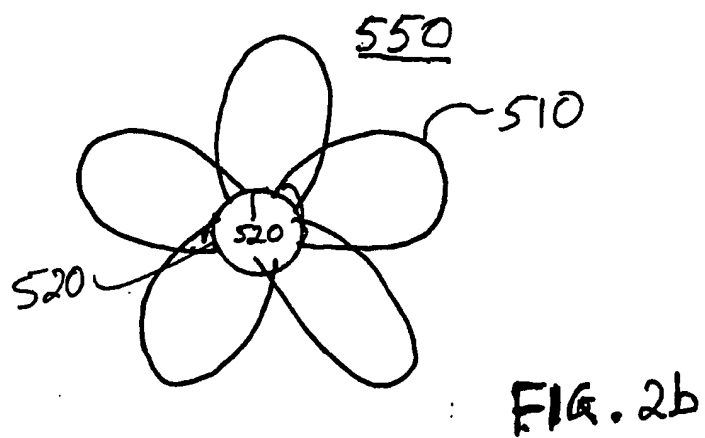
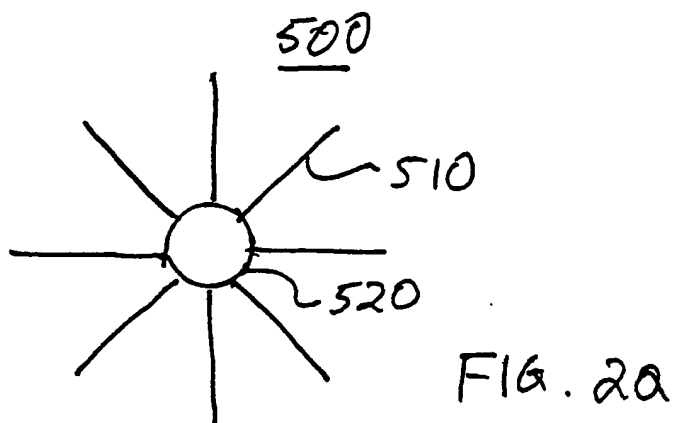
35. The method of claim 34 wherein providing said tube assembly further comprises providing a positioning tube that retractably extends through said delivery tube, and wherein said positioning guide is disposed on an end of said positioning tube

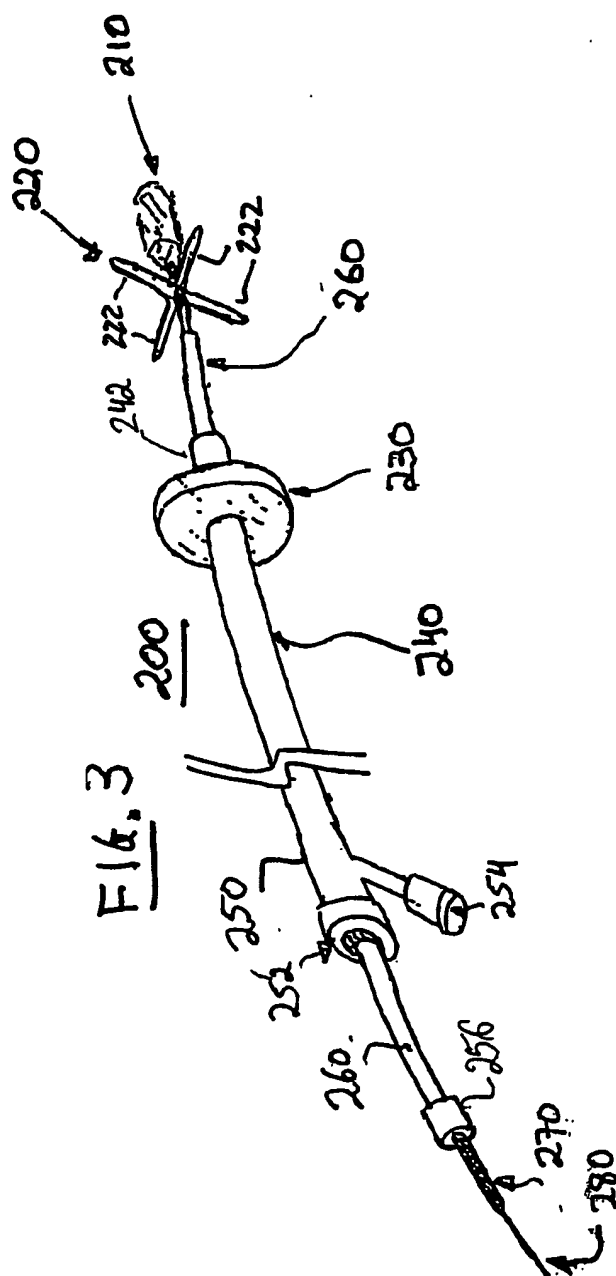
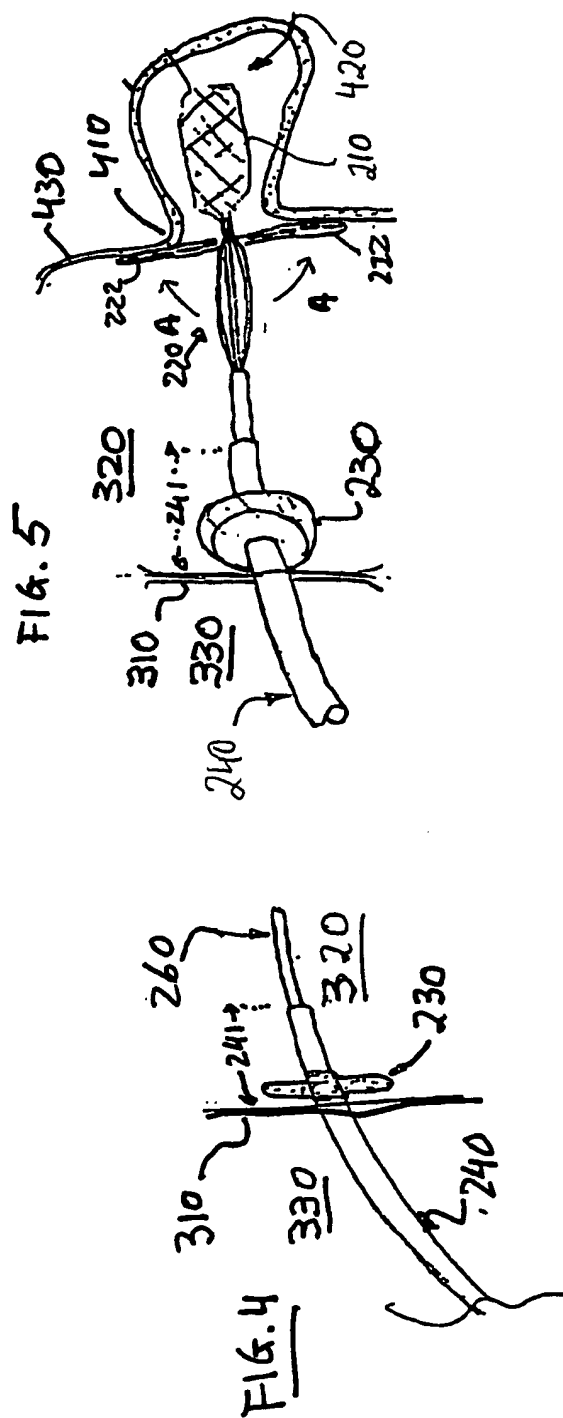
36. The method of claim 28 wherein providing said tube assembly further comprises providing a securement means disposed on an end of said outer tube, and wherein said securement means engages surface portions of a septum traversed by said outer tube to restrain further movement of said outer tube.

37. The method of claim 36 wherein providing said securement means further comprises providing a securement means having a reversibly expandable structure.

38. The method of claim 37 wherein providing said securement means having a reversibly expendable structure comprises providing an inflatable structure made from an elastic membrane.







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(72) Inventors: **BORILLO, Thomas, E.**; 19035 31st Avenue North, Plymouth, MN 55447 (US). **SUTTON, Gregg, S.**; 9136 Lanewood Court, Maple Grove, MN 55369 (US).

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GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations

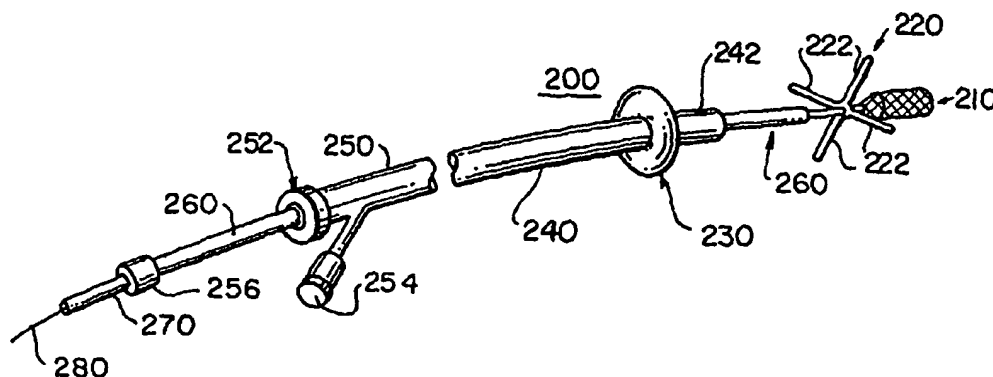
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(54) Title: APPARATUS FOR IMPLANTING DEVICES IN ATRIAL APPENDAGES



(57) Abstract: The invention provides a delivery system for placing devices in atrial appendages. The system includes a catheterization apparatus having a tubular structure with one or more nested tubes, wires, and shafts. The tubes establish a passageway for moving a device through a body's vasculature and heart into an atrial appendage. An expandable positioning guide is disposed on the distal end of a tube passing through the apparatus. The positioning guide is expanded in situ to engage atrial wall surfaces proximate to the atrial appendage for mechanical stabilization of the device delivery passageway. A shaft passing through the tubes transports the device through the passageway to the atrial appendage.

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INTERNATIONAL SEARCH REPORT

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PCT/JS 01/29690

A. CLASSIFICATION OF SUBJECT MATTER		
IPC 7	A61F2/01	A61F2/06 A61B17/34 A61B17/00 A61B17/12
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
IPC 7 A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the International search (name of data base and, where practical, search terms used)		
EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 865 791 A (FLEISCHMAN SIDNEY D ET AL) 2 February 1999 (1999-02-02) claims; figures	1-8, 17-27
P,A	WO 01 30268 A (ATRITECH INC) 3 May 2001 (2001-05-03) cited in the application claims; figures	1-8, 17-27
P,A	WO 01 30267 A (ATRITECH INC) 3 May 2001 (2001-05-03) cited in the application claims; figures	1-8, 17-27
P,A	WO 01 30266 A (ATRITECH INC) 3 May 2001 (2001-05-03) cited in the application claims; figures	1-8, 17-27
		-/--
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents : *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art *Z* document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
2 September 2002		10/09/2002
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Kuehne, H-C

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INTERNATIONAL SEARCH REPORT

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PCT/US 01/29690

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00 27292 A (MV MEDICAL DEVICES INC) 18 May 2000 (2000-05-18) claims; figures	1-8, 17-27

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/29690

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 9-16 28-38
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 01/29690

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5865791	A	02-02-1999	CA 2223152 A1	19-12-1996
			EP 0836507 A1	22-04-1998
			JP 11507262 T	29-06-1999
			WO 9640356 A1	19-12-1996
WO 0130268	A	03-05-2001	AU 1232701 A	08-05-2001
			AU 2119501 A	08-05-2001
			AU 2299001 A	08-05-2001
			EP 1227770 A1	07-08-2002
			EP 1223890 A1	24-07-2002
			EP 1225843 A1	31-07-2002
			WO 0130266 A1	03-05-2001
			WO 0130267 A1	03-05-2001
WO 0130267	A	03-05-2001	AU 1232701 A	08-05-2001
			AU 2119501 A	08-05-2001
			AU 2299001 A	08-05-2001
			EP 1227770 A1	07-08-2002
			EP 1223890 A1	24-07-2002
			EP 1225843 A1	31-07-2002
			WO 0130266 A1	03-05-2001
			WO 0130267 A1	03-05-2001
WO 0130266	A	03-05-2001	AU 1232701 A	08-05-2001
			AU 2119501 A	08-05-2001
			AU 2299001 A	08-05-2001
			EP 1227770 A1	07-08-2002
			EP 1223890 A1	24-07-2002
			EP 1225843 A1	31-07-2002
			WO 0130266 A1	03-05-2001
			WO 0130267 A1	03-05-2001
WO 0027292	A	18-05-2000	US 6152144 A	28-11-2000
			AU 1715300 A	29-05-2000
			CN 1342056 T	27-03-2002
			EP 1135068 A1	26-09-2001
			WO 0027292 A1	18-05-2000

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(72) Inventors: BORILLO, Thomas, E.; 19035 31st Avenue North, Plymouth, MN 55447 (US). SUTTON, Gregg, S.; 9136 Lanewood Court, Maple Grove, MN 55369 (US).

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GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

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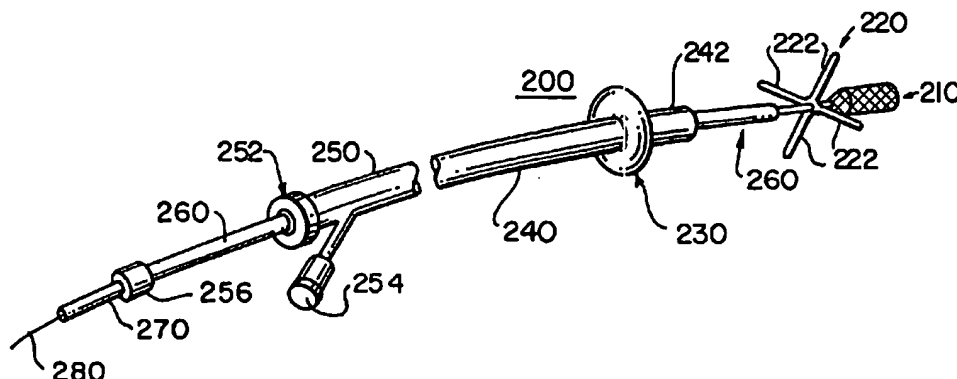
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[Continued on next page]

(54) Title: APPARATUS FOR IMPLANTING DEVICES IN ATRIAL APPENDAGES



(57) Abstract: The invention provides a delivery system for placing devices in atrial appendages. The system includes a catheterization apparatus having a tubular structure with one or more nested tubes, wires, and shafts. The tubes establish a passageway for moving a device through a body's vasculature and heart into an atrial appendage. An expandable positioning guide is disposed on the distal end of a tube passing through the apparatus. The positioning guide is expanded in situ to engage atrial wall surfaces proximate to the atrial appendage for mechanical stabilization of the device delivery passageway. A shaft passing through the tubes transports the device through the passageway to the atrial appendage.

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(15) Information about Correction:

see PCT Gazette No. 46/2003 of 13 November 2003, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

APPARATUS FOR IMPLANTING DEVICES
IN ATRIAL APPENDAGES

This application claims the benefit of U.S.
5 provisional application No. 60/234,111, filed September
21, 2000, which is hereby incorporated by reference in
its entirety herein.

Background of the Invention

Field of the Invention

10 The invention relates to apparatus for
implanting devices in atrial appendages. The devices
may be used to filter or otherwise modify blood flow
between the atrial appendage and an associated atrium
of the heart to prevent thrombi from escaping from the
15 atrial appendage into the body's blood circulation
system. In particular the invention relates to
apparatus for percutaneous delivery and implantation of
such devices.

Description of the Related Art

20 There are a number of heart diseases (e.g.,
coronary artery disease, mitral valve disease) that
have various adverse effects on a patient's heart. An
adverse effect of certain cardiac diseases, such as
mitral valve disease, is atrial (or auricular)

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fibrillation. Atrial fibrillation leads to depressed cardiac output. A high incidence of thromboembolic (i.e., blood clot particulate) phenomena is associated with atrial fibrillation, and the left atrial appendage
5 (LAA) is frequently the source of the emboli (particulates).

Thrombi (i.e., blood clots) formation in the LAA may be due to stasis within the fibrillating and inadequately emptying LAA. Blood pooling in the atrial
10 appendage is conducive to the formation of blood clots. Blood clots may accumulate and build upon themselves. Small or large fragments of the blood clots may break off and propagate out from the atrial appendage into the atrium. The blood clot fragments can then enter
15 the body's blood circulation and embolize distally into the blood stream.

Serious medical problems result from the migration of blood clot fragments from the atrial appendage into the body's blood stream. Blood from the
20 left atrium and ventricle circulates to the heart muscle, the brain, and other body organs, supplying them with necessary oxygen and other nutrients. Emboli generated by blood clots formed in the left atrial appendage may block the arteries through which blood
25 flows to a body organ. The blockage deprives the organ tissues of their normal blood flow and oxygen supply (ischemia), and depending on the body organ involved leads to ischemic events such as heart attacks (heart muscle ischemia) and strokes (brain tissue ischemia).

30 It is therefore important to treat cardiac conditions to prevent fragments or emboli generated by any blood clots that may have formed in the atrial appendages, from propagating through the blood stream to the heart muscle, brain or other body organs.

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Some recently proposed methods of treatment are directed toward implanting a plug-type device in an atrial appendage to occlude the flow of blood therefrom.

5 A preventive treatment method for avoiding thromboembolic events (e.g., heart attacks, strokes, and other ischemic events) involves filtering out harmful emboli from the blood flowing out of atrial appendages. Co-pending and co-owned U.S.
10 patent application No. 09/428,008, U.S.
patent application No. 09/614,091, U.S.
patent application No. 09/642,291, U.S.
patent application No. 09/697,628, and U.S.
15 patent application No. 09/932,512, all of which are hereby incorporated by reference in their entireties herein, describe expandable filtering devices which may be implanted in an atrial appendage to filter the blood flow therefrom.

The implant devices in a compact state may be
20 delivered to their atrial appendage situs percutaneously through femoral or jugular blood vessels using conventional catheterization apparatus. The position of an implanted device may be observed using common imaging techniques, for example, radiography or
25 echocardiography. The implant devices are deployed by expanding them in situ. The devices are retained in position by expandable structures which engage surrounding atrial appendage tissue. The expandable structures may include tissue piercing anchors.

30 To function effectively the devices must be deployed from suitable positions within or about the atrial appendages. For example, the filter elements of a device must be correctly centered or positioned across an atrial appendage ostium for the device to

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properly intercept and filter blood flowing out of the atrial appendage. Placing a device in a suitable deployment position may require position probing or adjustment from an initial as-delivered position.

5 It would therefore be desirable to provide catheterization apparatus having positioning guides, which enable controlled position probing and readjustment of the initial as-delivered implant device position to place the device in a suitable deployment
10 position in the atrial appendage.

 Further, the implant procedures may include transseptal catheterization which involves puncturing an atrial septum and advancing an access sheath through the septum. The access sheath provides a conduit
15 through which an implant device may be delivered across the septum into the adjoining atrium. Inadvertent movement of the sheath during the catheterization procedure may lead to undesirable medical complications. For example, retrograde slippage may
20 cause the sheath to disengage from the septum, which in turn may necessitate repeated puncturing or crossing of the septum to regain access to the adjoining atrium. Further, instability in the position or orientation of the access sheath may make the delivery of a device for
25 placement in an appendage geometrically difficult.

 It would therefore also be desirable to provide transseptal catheterization apparatuses which include securement devices for restraining the movement of and securing the position of the access sheath
30 traversing the septum.

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Summary of the Invention

The invention provides a catheterization apparatus having a positioning device or guide, which enables controlled position probing and readjustment of the initial as-delivered implant device position. The catheterization apparatus may include one or more nested tubes, wires or shafts. The positioning guide may be attached to a positioning tube passing through the catheter apparatus. Using the positioning guide, the implant device position in the atrial appendage may be readjusted from the as-delivered position to a desired deployment position.

The positioning guide may have an expandable structure. The structure may be expandable from a compact state to an expanded state. The positioning guide is delivered in its compact state to a location adjoining the ostium of an atrial appendage. The apparatus may include size-adjusting mechanisms for expanding the positioning guide in situ. The positioning guide may be deployed by expanding it to engage or contact portions of the atrial wall proximate to the ostium for mechanical support. The deployed guide thereby holds and stabilizes outer portions of the catheter apparatus in a fixed position. An implant device attached to a shaft passing through the catheterization apparatus may then be reversibly positioned within the atrial appendage. The implant device position may be monitored, for example, by echocardiography, radiography or fluoroscopy. After the implant device is suitably positioned and deployed, the positioning guide may be contracted to its compact non-expanded state and retracted.

In an embodiment of the catheterization apparatus which may be useful for transseptal

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catheterization, a securement means is attached to an access sheath in the catheterization apparatus. The access sheath is used to puncture an atrial septum and then advanced through the puncture to provide a passage way through which an implant device may be delivered to an adjoining atrium. The securing means may, for example, include an inflatable disk having an inflated diameter that is larger than the size of the septal puncture. The inflatable disk may be deployed to engage distal surfaces of the punctured septum to secure the position of the access sheath relative to the septum.

Other embodiments of the positioning guides (and securement means) may have other kinds of inflatable or expandable structures which allow the positioning devices (and securement means) to have compact sizes for delivery and which can later be enlarged in situ.

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawing and the following detailed description.

Brief Description of the Drawings

FIG. 1 is a partial cross sectional view of a heart illustrating a conventional catheter entering a left atrial appendage using a transseptal procedure.

FIGS. 2a and 2b illustrate examples of wire patterns or configurations of expanded positioning guides in accordance with the principles of the invention

FIG. 2c schematically illustrates an inflatable balloon-type positioning guide in accordance with the principles of the invention.

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FIG. 3 is a schematic view of a portion of a transseptal catheterization apparatus having a positioning guide for reversible or adjustable placement of an implant device in an atrial appendage, and a securement means for restraining movement of a septum-traversing access sheath in accordance with the principles of the invention.

FIG. 4 is a schematic view of a portion of the transseptal catheterization apparatus of FIG. 3 illustrating the deployment of the securement means to restrain movement of a septum-traversing sheath in accordance with the principles of the invention.

FIG. 5 is a schematic view of a portion of the transseptal catheterization apparatus of FIG. 3 illustrating figuratively the deployment of the positioning guide to engage atrial wall surfaces proximate to the ostium of an atrial appendage in accordance with the principles of the invention.

Description of the Preferred Embodiments

Implant devices for filtering or otherwise modifying blood flow between an atrial appendage and its atrium may be attached to a catheter shaft and then be percutaneously delivered to the appendage through a blood vessel leading to the heart.

FIG. 1 illustrates, for example, catheter 21 inserted through a femoral vein (not shown) entering the right atrium of the heart through the inferior vena cava 18, and then passing into left atrium 11 through the fossa ovalis 19 or through the septum 29 before entering the left atrial appendage 13. Alternatively (not shown in FIG. 1), catheter 21 may enter the left ventricle 16 of the heart through the aorta 12, and then pass through mitral valve 17 to reach left atrial

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appendage 13. An implant device (not shown) attached to catheter 21 may be used to prevent thrombus 30 or emboli generated therefrom from migrating into atrium 11. The device may include materials having
5 suitable properties (e.g., radio-opacity) that make it possible to monitor the in-vivo device position during and after the catheterization position using external imaging techniques such as radiography or fluoroscopy, echocardiography, and ultrasound.

10 The present invention provides a catheterization apparatus having a positioning device or guide, which enables controlled position probing and readjustment of an initial as-delivered implant device position. The implant device position in the atrial
15 appendage may be readjusted from the as-delivered position to a desired deployment position. The catheterization apparatus may include one or more nested tubes, wires or shafts. The positioning guide may be attached to a positioning tube passing through
20 the catheter apparatus.

 The positioning guide may have an expandable or inflatable structure designed to engage (contact) atrial wall portions surrounding the ostium. The structure may be designed to be reversibly expandable
25 from a compact state suitable for percutaneous delivery and withdrawal. Further, the positioning guide may be designed to engage surrounding atrial wall portions to provide a stable and reproducible pathway for movement of a device-carrying shaft in and out of the atrial
30 appendage.

 The positioning guide may be made of suitable biocompatible materials including metals and polymeric materials such as ePFTE (e.g., Gortex®), polyester (e.g., Dacron®), PTFE (e.g., Teflon®), stainless steel

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and shape-memory alloys (e.g., nitinol) fibers or wires.

Positioning guides according to one embodiment may be formed from lengths of wires. The wires may be made of suitable elastic materials including shape memory alloy materials such as nitinol. There may be one or more wires or wire configurations which make up the positioning guide. In the compact state of the positioning guide that is suitable for percutaneous delivery, the wires may lie substantially along the positioning tube. The wires or wire configurations made, for example, from shape-memory alloy materials, may have preformed shapes. In the expanded state of the positioning guides, these wires may revert to their preformed shapes in which they may extend away from the positioning tube. The extended wires may have any suitable configuration for engaging the atrial wall portions. For example, the extended wires may have a straight spoke-like pattern or have more complex patterns such as overlapping arcuate patterns. FIG. 2a illustrates, for example, a spoke-like configuration of wires 510 in the expanded or deployed state of a positioning guide 500. Wires 510 extend radially outward away from positioning tube 520 on which guide 500 is disposed. Further, for example, FIG. 2b illustrates an overlapping arcuate pattern of wires 510 in the expanded or deployed state of positioning guide 550.

The catheterization apparatus may include suitable size-adjusting mechanisms that allow the positioning guide to be reversibly expanded in situ. For example, the apparatus may include a retractable sleeve which covers and holds the elastic or shape-memory alloy wires forming a positioning guide in

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a compact configuration along or in close proximity to the positioning tube. The positioning guide may be deployed by retracting the sleeve to allow the wires to expand or unfurl radially outward. The sleeve may be
5 moved forward to reverse the expansion as needed to return the positioning guide to its compact state. Alternatively, the wires may be contained within the delivery tube, and attached, for example, to a sliding push rod that enables the wires to be retractably
10 extended through small diameter openings or holes in the delivery tube walls.

The positioning guide in its non-expanded compact state is delivered to a location adjoining the ostium of an atrial appendage. The positioning guide
15 is deployed by expanding it to engage or contact portions of the atrial wall proximate to the ostium for mechanical support. The outermost engagement points may be separated by distances that are larger than the positioning tube diameter. Preferably, the separation
20 distances are several times larger than the positioning tube diameter to obtain a support configuration having a wide geometry that favors mechanical stability. Additionally, the position guide may be suitably advanced forward to bear upon the atrial wall portions
25 with a contact pressure adequate to generate frictional resistance to its lateral movement. Thus, the deployed positioning guide may mechanically hold and stabilize the positioning tube in a fixed position relative to the ostium. An implant device attached to a shaft
30 passing through the positioning tube may then be reversibly placed at a location within the atrial appendage. The implant device position may be monitored, for example, by electrocardiographic, radiographic, or fluoroscopic imaging. After the

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implant device is suitably positioned or deployed, the positioning guide may be contracted and retracted.

Other embodiments of the positioning guides may have other kinds of inflatable or expandable
5 structures which allow the positioning guides to have compact sizes for delivery and which can later be enlarged in situ. For example, positioning guides according to one of these other embodiments may have inflatable balloon-type structures. The balloons may
10 be made of suitable elastic membranes, for example, made of urethane or silicone material. FIG. 2c schematically illustrates, for example, a balloon-type structure 560 of a positioning guide 570.

An embodiment of a catheterization apparatus
15 may be useful for transseptal catheterization. The apparatus of this embodiment has an access sheath which is used to provide a conduit or pathway for device delivery across a septum between adjoining atriums. The apparatus includes a securement means which may be
20 used to restrain movement of the septum-traversing access sheath. The securement means is disposed on or about the distal end of the access sheath.

The access sheath may be an outermost tube of the catheterization apparatus. Known catheterization
25 techniques may be used to have the access sheath penetrate and traverse a septum. A known technique, for example, uses a conventional dilator (obturator) device having a covered needle in its tip. The dilator is preloaded in the access sheath such that the dilator
30 tip extends out of the distal end of the access sheath. The preloaded access sheath is advanced into an atrium through the body's vasculature. Next, the dilator needle is advanced through the dilator tip to puncture the atrial septum, following which the dilator itself

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is advanced to dilate the puncture opening. The access sheath is then advanced through the dilated puncture opening across the septum into the adjoining atrium. Finally, the dilator device is then withdrawn from the
5 access sheath.

The securement means in the catheterization apparatus of the present invention may be deployed to restrain further movement of the septum-traversing access sheath. The securing means may, for example,
10 include an inflatable disk having an inflated diameter that is larger than that size of the septal puncture or the diameter of the access tube. Preferably, the inflated diameter is several times larger than the diameter of the access tube. In catheterization
15 apparatus useful for procedures on adult hearts, the inflated diameter may, for example, be in the range of about 5 to 10 mm. The inflatable disk may be fabricated from membranes made of biocompatible materials such as silicone, urethane, or other
20 biocompatible polymers.

The catheterization apparatus may include suitable means for reversibly inflating the securement means. For example, the access sheath may include a tube connected to the inflatable disk structure through
25 which pressurizing fluids may be supplied to inflate the disk. The inflatable disk may be deployed to engage the distal surfaces of the punctured septum to secure the position of the access sheath relative to the septum and to restrain inadvertent movement of the
30 access sheath.

Other embodiments of the securement means may have other kinds of inflatable or expandable structures which allow the securement means to have compact sizes for delivery and which can later be enlarged in situ.

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FIG. 2 illustrates, for example, transseptal catheterization apparatus 200 having a positioning guide 220 for reversible placement of an implant device 210 in an atrial appendage, and a securement means 230 for restraining inadvertent or uncontrolled movement of a septum-traversing access sheath 240.

Apparatus 200 includes coaxially nested access sheath 240, delivery tube 260, positioning tube 270, and device shaft 280, all of which are connected to or pass through handle manifold 250.

Access sheath 240 may form an outer tubular structure of catheterization apparatus 200. Rigid biocompatible tube materials such as metals and plastics may be used to fabricate access sheath 240. However, access sheath 240 may be sufficiently flexible for it to course through blood vessels leading to the heart. Access sheath 240 may have an outer diameter suitable for percutaneous passage to the heart through readily accessible blood vessels, for example, the femoral veins.

One end (proximal end) of access sheath 240 is attached to handle manifold 250. Inflatable securement means 230 is disposed on or built into access sheath 200 toward its distal end. Securement means 230 may be reversibly inflated, for example, by pressurizing fluids injected through inflation port 254 disposed on manifold 250.

Handle manifold 250 includes fluid seal structure 252 through which a delivery tube 260 passes through and retractably extends into access sheath 240. Fluid seal 252 may be any conventional seal designed to prevent leakage of fluids while delivery tube 260 is retracted or extended into access sheath 240. Fluid seal 252 may, for example, be a

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conventional hemostatic seal. Rigid biocompatible tube materials such as metals and plastics similar to those used to fabricate access sheath 240 also may be used to fabricate delivery tube 260. Delivery tube 260 may
5 have sufficient flexibility for it to course through access sheath 240 in the latter's deployed position through blood vessels leading to the heart. Delivery tube 260 may have an outer diameter sized to allow its smooth movement within access sheath 240. The outer
10 diameter of delivery tube 260 also may be sufficiently smaller than the inner diameter of access sheath 240 to allow pressurizing fluids to flow between securement means 230 and inflation port 254. Alternatively or additionally, the outer surface of delivery tube 260
15 may be grooved to provide flow channels for pressurizing fluids to flow between securement means 230 and inflation port 254.

The inner diameter of delivery tube 260 is sized to be sufficiently large to accept and allow
20 passage of positioning guide 220 disposed on the distal end of a positioning tube 270. Rigid biocompatible tube materials such as metals and plastics similar to those used to fabricate access sheath 240 and delivery tube 260 also may be used to fabricate positioning tube
25 270. Positioning tube 270 may be sufficiently flexible for it to course through delivery tube 260 in the latter's deployed position through access sheath 240. Positioning tube 270 retractably extends into delivery tube 260 through seal 256 disposed on the proximal end
30 of delivery tube 260. Seal 256 is designed to prevent fluid leakage, and may, for example, be of a type similar to fluid seal 252.

Positioning guide 220 disposed on the distal end of positioning tube 270 may have a compact state

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from which it may be reversibly expanded to an expanded state. FIG. 2 shows for purposes of illustration an exemplary positioning guide 220 in its expanded state. Expanded positioning guide 220 has a structural configuration with four extended fingers 222 suitable for engaging or contacting atrial walls for mechanical support to stabilize the position of positioning tube 270. The four extended fingers shown in FIG. 3 have a size which is substantially larger than the diameter of delivery tube 260. However, it will be understood that positioning guide 220 is passable through delivery tube 260 only when the former is in its compact retracted state. Positioning tube 270 may include means such as a trip wire, a push rod, a retractable sleeve, or other suitable means to reversibly deploy positioning guide 220. Positioning tube 270 itself may, for example, serve as a push rod, in which case positioning guide 220 may be expanded or contracted by respectively advancing or retracting positioning tube 270 through delivery tube 260.

The inner diameter of positioning tube 270 is sized to be sufficiently large to accept and allow passage of compacted implant device 210 attached to one end of a device shaft 280. Implant device 210 may, for example, be any one of the self-expanding or inflatable filtering devices disclosed U.S. patent application No. 09/428,008, U.S. patent application No. 09/614,091, U.S. patent application No. 09/642,291, U.S. patent application No. 09/697,628, and U.S. patent application No. 09/932,512, incorporated by reference herein. Device shaft 280 may be a conventional catheter shaft having conventional fixtures for device attachment. Device shaft 280 may, for example, have a solid or tubular structure made of

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solid metals, metal braids, solid polymers, polymer braids, or any suitable combination thereof. Shaft 280 may enclose other tubes or structures that may be required for device deployment. For example, device
5 shaft 280 may include some lumen for supplying fluids for inflation of an expandable balloon in a balloon-inflatable type of device 210.

Catheterization apparatus 200 (or other embodiments thereof) may be used to controllably and
10 adjustably place an implant device at a suitable deployment location within an atrial appendage. Position guide 220 and/or securement means 230 may be used to provide a mechanically stable pathway for delivery of the device, and for adjusting the device
15 location within the atrial appendage before device deployment.

With reference to FIG. 4, in a transseptal catheterization procedure, access sheath 240 with securement means 230 in its compact state is introduced
20 into a right atrium 330 through the body's vasculature. The progress of access sheath 240 through the body may be monitored, for example, by echocardiography, radiographic or fluoroscopic imaging. A conventional needle and dilator assembly (not shown) reversibly
25 sliding through access sheath 240 may be used to puncture and dilate septum 310. Access sheath 240 is advanced forward through the dilated puncture opening in septum 310. A distal length 241 of access sheath 240 is advanced across septum 310 into left atrium 320.
30 After securement means 230 disposed on the distal end of access sheath 240 advances across septum 310, forward advancing motion of access sheath 240 may be halted. Securement means 230 may then be deployed, for example, by injecting pressurizing fluid through

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inflation port 254. With securement means 230 inflated movement of access sheath 240 is restrained by engagement of means 230 with distal wall surfaces of septum 310. This engagement may prevent retrograde
5 movement or slippage of access sheath 300 that may occur inadvertently, or for example, in mechanical reaction to the action of advancing other strictures such as a tight fitting delivery tube 260 through access sheath 230. FIG. 4 shows access sheath 240 with
10 length 241 jutting into left atrium 320 secured against septum 310 by inflated securement means 230, and providing a mechanically stable conduit for delivery tube 260 to access left atrium 320.

Implant device 210 and other catheter
15 structures including positioning guide 220 may be passed through delivery tube 260 into left atrium 320. FIG. 5 figuratively illustrates the deployment of the positioning guide 220 to engage atrial wall surfaces 430 proximate to the ostium 410 of a left
20 atrial appendage 420 for mechanical support.

After access sheath 240 is secured against septum 310 by inflated securement means 230, and delivery tube 260 is introduced into left atrium 320, positioning tube 270 with positioning guide 220 in its
25 compact state is advanced through delivery tube 260 into left atrium 320. Positioning tube 270 is advanced sufficiently into left atrium 320 so that positioning guide 220 butts up against or is very close ostium 410. Positioning guide 220 is then deployed so that it
30 engages surface portions of the atrial wall 430 surrounding ostium 410. In FIG. 5, directions A figuratively depict the motion of fingers 222 during the deployment of guide 220. During the deployment fingers 222 move from a contracted configuration

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alongside positioning tube 270 to an expanded configuration with fingers 222 spread radially outward. Fingers 222 in the expanded configuration engage atrial wall 430 for mechanical support. By engaging or
5 contacting atrial wall 430 positioning guide 220 mechanically stabilizes the position of tubes 260 and 270 relative to that of atrial appendage 420. Implant device 210 attached to shaft 280 may be delivered to a location within atrial appendage 420 simultaneously
10 with the delivery of positioning guide 220 to a location butting up against or is very close ostium. Alternatively, implant device 210 may be delivered after positioning guide 220 has been deployed to engage atrial walls 430 for mechanical support. The location
15 of device 210 may be adjusted by sliding shaft 280 through the stabilized pathway provided by positioning tube 270 held in relatively fixed position by deployed positioning guide 220.

It will be understood that the foregoing is
20 only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. It will be understood that terms like "distal" and "proximal", and other
25 directional or orientational terms are used herein only for convenience, and that no fixed or absolute orientations are intended by the use of these terms.

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What Is Claimed Is:

1. A catheterization apparatus for transseptal delivery of a device, comprising:
a sheath for traversing a septum and establishing a transseptal conduit for passage of said device across said septum;
securement means disposed on said sheath for restraining movement of said sheath relative to said traversed septum; and
a shaft for transporting said device through said sheath across said septum.
2. The apparatus of claim 1 wherein said sheath comprises a flexible tube.
3. The apparatus of claim 1 wherein said securement means comprises a reversibly expandable structure.
4. The apparatus of claim 3 wherein said reversibly expandable structure when expanded engages surface portions of said traversed septum.
5. The apparatus of claim 3 wherein said expandable structure comprises an inflatable structure.
6. The apparatus of claim 5 wherein said sheath further comprises lumen for supplying pressurizing fluids to inflate said inflatable structure.
7. The apparatus of claim 5 wherein said inflatable structure is made from an elastic membrane.

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8. The apparatus of claim 5 wherein said inflatable structure has an inflated diameter that is several times larger than the diameter of said sheath.

9. A method for establishing a transseptal conduit for device delivery during a catheterization procedure, comprising:

providing a catheterization apparatus comprising:

a sheath for traversing a septum wherein said sheath comprises lumen for movement of a device therethrough; and

securement means disposed on said sheath for restraining movement of said sheath relative to said traversed septum;

puncturing and dilating said septum;

advancing said sheath through said punctured septum to move said securement means across said septum; and

deploying said securement means to engage surface portions of said septum and thereby restrain further movement of said sheath.

10. The method of claim 9 wherein said providing a catheterization apparatus further comprises providing said sheath in the form of a flexible tube.

11. The method of claim 9 wherein said providing a catheterization apparatus further comprises providing said securement means having a reversibly expandable structure.

12. The method of claim 11 wherein said providing said securement means having a reversibly

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expandable structure further comprises providing a structure which when expanded engages surface portions of said traversed septum.

13. The method of claim 11 wherein said providing said securement means having a reversibly expandable structure further comprises providing an inflatable structure.

14. The method of claim 13 wherein providing said sheath further comprises providing a sheath having lumen for supplying pressurizing fluids to inflate said inflatable structure.

15. The method of claim 13 wherein providing said inflatable structure further comprises providing an inflatable structure made from an elastic membrane.

16. The method of claim 13 wherein providing said inflatable structure further comprises providing an inflatable structure having an inflated diameter that is several times larger than the diameter of said sheath.

17. A catheterization apparatus for implanting a device in an atrium's appendage, comprising:

a tube assembly for providing a passage way for movement of said device through the body's vasculature and said atrium to said appendage, said assembly comprising at least an outer tube;

a shaft for transporting said device through said assembly; and

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a positioning guide for engaging atrial wall portions for mechanical support of portions of said tube assembly within said atrium.

18. The apparatus of claim 17 wherein said positioning guide is disposed on a positioning tube that retractably extends through said outer tube.

19. The apparatus of claim 17 wherein said positioning guide comprises a reversibly expandable structure.

20. The apparatus of claim 19 wherein said reversibly expandable structure comprises at least a preformed wire configuration.

21. The apparatus of claim 19 wherein said reversibly expandable structure comprises an inflatable balloon.

22. The apparatus of claim 21 wherein said tube assembly further comprises lumen for supplying pressurizing fluids to inflate said inflatable structure.

23. The apparatus of claim 17 wherein said tube assembly further comprises a delivery tube for advancing said positioning guide through said tube assembly to a location proximate to said appendage, wherein said delivery tube retractably extends through said outer tube.

24. The apparatus of claim 23 wherein said tube assembly further comprises a positioning tube that

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retractably extends through said delivery tube wherein said positioning guide is disposed on an end of said positioning tube.

25. The apparatus of claim 17 further comprising a securement means disposed on an end of said outer tube wherein said securement means engages surface portions of a septum traversed by said outer tube to restrain further movement of said outer tube.

26. The apparatus of claim 25 wherein said securement means comprises a reversibly expendable structure.

27. The apparatus of claim 26 wherein said expandable structure is an inflatable structure made from an elastic membrane.

28. A method for implanting a device in an atrium's appendage, comprising
providing a catheterization apparatus
comprising:

a tube assembly for providing a passage way for movement of said device through the body's vasculature and through said atrium to said appendage, said assembly comprising at least an outer tube;

a shaft for transporting said device through said assembly; and

a positioning guide for engaging atrial wall portions for mechanical support of portions of said sheath assembly within said atrium;

percutaneously advancing said tube assembly through a blood vessel to establish a passageway to said atrium;

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introducing said positioning guide to a location about the ostium of said appendage;

deploying said positioning guide to engage atrial wall portions for mechanical support; and

using said shaft to transport said device through said passageway to a position within said appendage

29. The method of claim 28 wherein providing said catheterization apparatus further comprises providing a positioning guide that is disposed on a positioning tube that retractably extends through said outer tube.

30. The method of claim 28 wherein providing said positioning guide further comprises providing a positioning guide having a reversibly expandable structure.

31. The method of claim 30 wherein providing said reversibly expandable structure comprises providing at least a preformed wire configuration.

32. The method of claim 30 wherein providing said reversibly expandable structure comprises providing an inflatable balloon.

33. The method of claim 32 wherein providing said tube assembly further comprises providing lumen for supplying pressurizing fluids to inflate said inflatable balloon.

34. The method of claim 28 wherein providing said tube assembly further comprises providing a

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delivery tube for advancing said positioning guide through said tube assembly to a location proximate to said appendage, and wherein said delivery tube retractably extends through said outer tube.

35. The method of claim 34 wherein providing said tube assembly further comprises providing a positioning tube that retractably extends through said delivery tube, and wherein said positioning guide is disposed on an end of said positioning tube

36. The method of claim 28 wherein providing said tube assembly further comprises providing a securement means disposed on an end of said outer tube, and wherein said securement means engages surface portions of a septum traversed by said outer tube to restrain further movement of said outer tube.

37. The method of claim 36 wherein providing said securement means further comprises providing a securement means having a reversibly expandable structure.

38. The method of claim 37 wherein providing said securement means having a reversibly expendable structure comprises providing an inflatable structure made from an elastic membrane.

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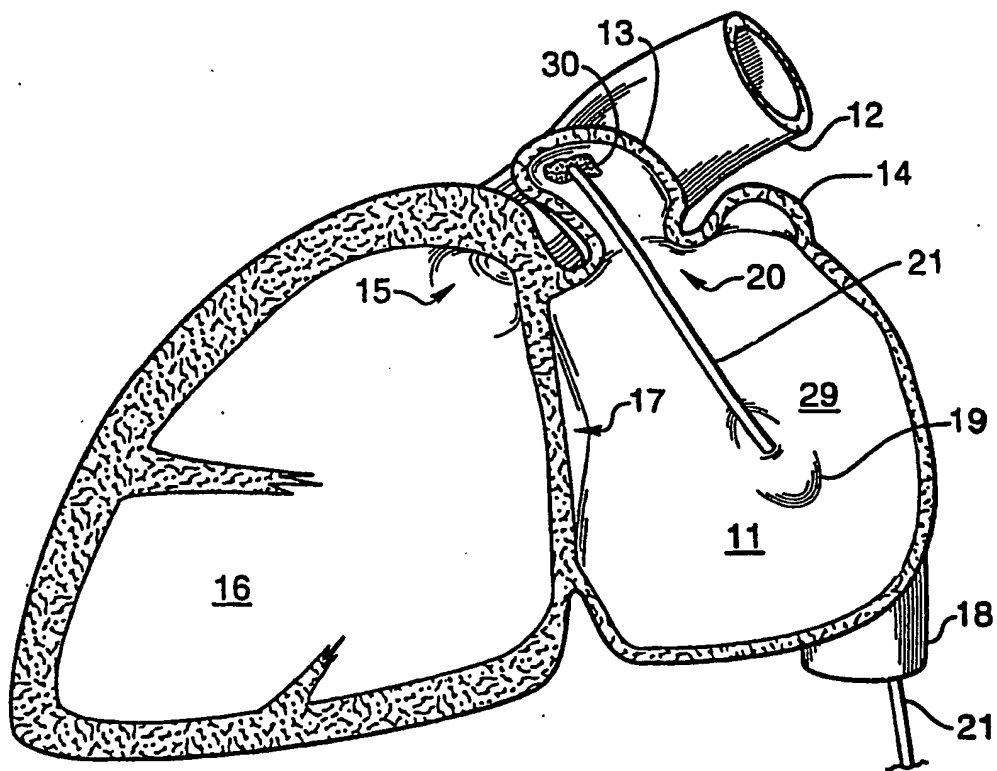
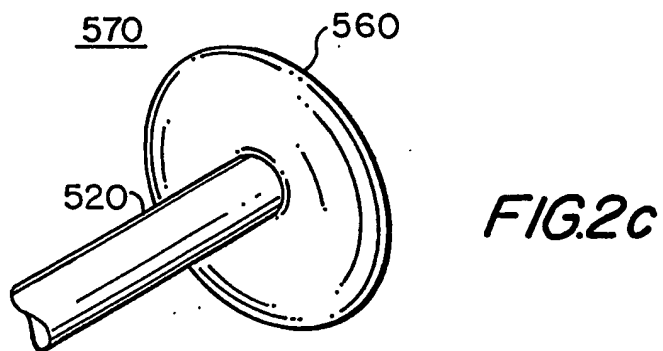
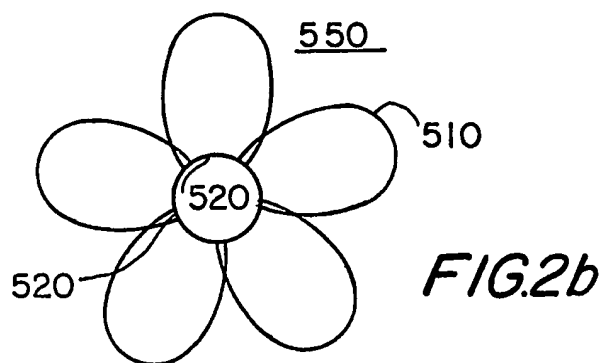
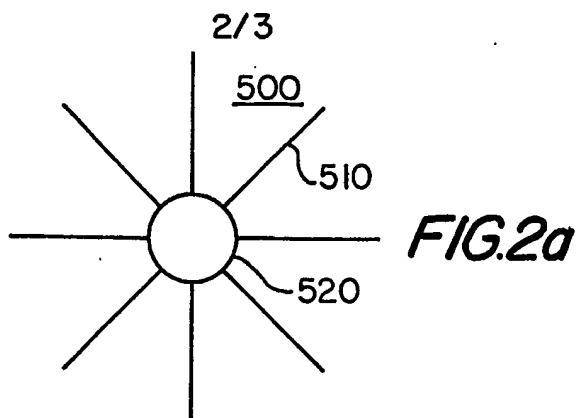


FIG. 1



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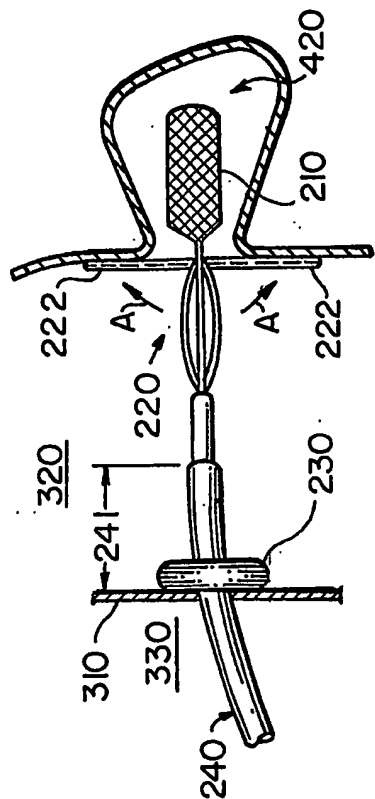


FIG. 5

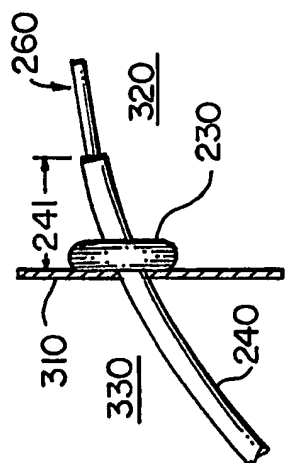


FIG. 4

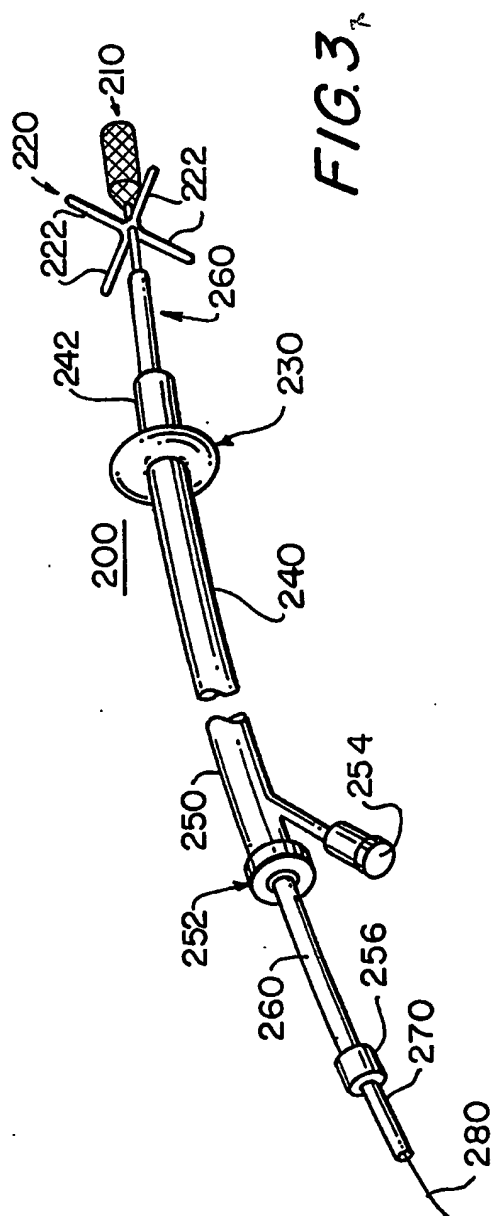


FIG. 3

International Application No
PCT/US 01/29690

IPC 7 A61F2/01 A61F2/06 A61B17/34 A61B17/00 A61B17/12

B. FIELDS SEARCHED

IPC 7 A61B

EPO-Internal

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 865 791 A (FLEISCHMAN SIDNEY D ET AL) 2 February 1999 (1999-02-02) claims; figures ---	1-8, 17-27
P,A	WO 01 30268 A (ATRITECH INC) 3 May 2001 (2001-05-03) cited in the application claims; figures ---	1-8, 17-27
P,A	WO 01 30267 A (ATRITECH INC) 3 May 2001 (2001-05-03) cited in the application claims; figures ---	1-8, 17-27
P,A	WO 01 30266 A (ATRITECH INC) 3 May 2001 (2001-05-03) cited in the application claims; figures ---	1-8, 17-27

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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

***&** document member of the same patent family

10/09/2002

Kuehne, H-C

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/29690

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00 27292 A (MV MEDICAL DEVICES INC) 18 May 2000 (2000-05-18) claims; figures -----	1-8, 17-27

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/29690

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 9-16 28-38
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/29690

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5865791	A	02-02-1999	CA 2223152 A1	19-12-1996
			EP 0836507 A1	22-04-1998
			JP 11507262 T	29-06-1999
			WO 9640356 A1	19-12-1996
WO 0130268	A	03-05-2001	AU 1232701 A	08-05-2001
			AU 2119501 A	08-05-2001
			AU 2299001 A	08-05-2001
			EP 1227770 A1	07-08-2002
			EP 1223890 A1	24-07-2002
			EP 1225843 A1	31-07-2002
			WO 0130266 A1	03-05-2001
			WO 0130267 A1	03-05-2001
			WO 0130268 A1	03-05-2001
WO 0130267	A	03-05-2001	AU 1232701 A	08-05-2001
			AU 2119501 A	08-05-2001
			AU 2299001 A	08-05-2001
			EP 1227770 A1	07-08-2002
			EP 1223890 A1	24-07-2002
			EP 1225843 A1	31-07-2002
			WO 0130266 A1	03-05-2001
			WO 0130267 A1	03-05-2001
			WO 0130268 A1	03-05-2001
WO 0130266	A	03-05-2001	AU 1232701 A	08-05-2001
			AU 2119501 A	08-05-2001
			AU 2299001 A	08-05-2001
			EP 1227770 A1	07-08-2002
			EP 1223890 A1	24-07-2002
			EP 1225843 A1	31-07-2002
			WO 0130266 A1	03-05-2001
			WO 0130267 A1	03-05-2001
			WO 0130268 A1	03-05-2001
WO 0027292	A	18-05-2000	US 6152144 A	28-11-2000
			AU 1715300 A	29-05-2000
			CN 1342056 T	27-03-2002
			EP 1135068 A1	26-09-2001
			WO 0027292 A1	18-05-2000